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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,894	12/22/2004	Fukumi Morishige	122229	2882

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OLIFF & BERRIDGE, PLC
P.O. BOX 320850
ALEXANDRIA, VA 22320-4850

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
04/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,894	MORISHIGE, FUKUMI	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to preventing virus infection broadly, and preventing SARS in particular by administering arginine and vitamin C.

The disclosure teaches that:

> The prevention of viral infection by such a vaccine is, however, not always universal. Viruses always change their structures to yield new strains. A vaccine efficacious to a certain virus is not efficacious to a new strain of the virus which raised as a result of change in structure thereof. Among such viruses, RNA viruses severely change in their structures. There has been a report that coronavirus inducing SARS, for example, shows different nucleotide sequences between its strain in Hong Kong and that in Taiwan. Even if a vaccine efficacious for the prevention of SARS is developed, it may highly possibly become inefficacious immediately because of the rapid change in structure of the virus and is not promising. (0004).

Thus, preventing viral infection is very unpredictable and only known method for preventing virus infection is vaccination.

The disclosure assert that arginine is useful for enhancing immune function [0020], and vitamin C may useful for resolving fibrogenesis caused by viral infection. [0024]. The application provides no written description of factual bases supporting the assertion, and no rationale as how and why the combination of the two agents would be effective for preventing viral infection in general, and preventing SARS in particular.

The two working examples (examples 1 and 2) are drawn to treatment of patient suffering pulmonary diseases, and showing nothing about preventing viral infection.

Since there is no known method for preventing viral infection by administering agents other than vaccine, and since the application fails to set forth any fact and/or rationale that all viral infection, including SARS, HIV, hepatitis C, can be prevented by the claimed method, and thereby accomplish a task that skilled artisans have been trying for years but without a success, a skilled artisan would have reasonable doubt that appellants have possession of a such method.

3. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

4. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

5. The claims are drawn to preventing virus infection generally, and preventing SARS in particular by administering arginine and vitamin C.

The state of prior art: the disclosure reveals that

The prevention of viral infection by such a vaccine is, however, not always universal. Viruses always change their structures to yield new strains. A vaccine efficacious to a certain virus is not efficacious to a new strain of the virus which raised as a result of change in structure thereof. Among such viruses, RNA viruses severely change in their structures. There has been a report that coronavirus inducing SARS, for example, shows different nucleotide sequences between its strain in Hong Kong and that in Taiwan. Even if a vaccine efficacious for the prevention of SARS is developed, it may highly possibly become inefficacious immediately because of the rapid change in structure of the virus and is not promising. [0004].

Thus, preventing viral infection is very unpredictable and only known method for preventing virus infection is vaccination.

The disclosure assert that arginine is useful for enhancing immune function [0020], and vitamin C may useful for resolving fibrogenesis caused by viral infection. [0024]. The application provides no written description of factual bases supporting the assertion, and no rationale as how and why the combination of the two agents would be effective for preventing viral infection in general, and preventing SARS in particular. Thus, the application fails to provide sufficient guidance and/or direction to a skilled artisan as how to accomplish prevention of viral infection.

The two working examples (examples 1 and 2) are drawn to treatment of patient suffering pulmonary diseases, and showing nothing about preventing viral infection. Thus, the application provides no working examples for preventing viral infection.

Therefore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paul (US 5,626,883), Yoshimura et al. (US 5,576,351), and in further view of Koff et al. (US 3,247,065).

8. Paul et al. teaches that ascorbic acid is known to be useful for enhance human immune system activity. See, particularly, the abstract. Paul et al further teach a dietary composition comprising ascorbic acid and a base amino acid, such as arginine. See, particularly, claims 1-18. Yoshimura et al. teaches that arginine is particularly known as immunostimulator. See, particularly, the abstract.

9. The cited references do not teach expressly a composition comprising arginine and coated ascorbic acid (vitamin C).

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising both ascorbic acid and arginine because both are known to enhance immune system. It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art. See In re Kerkhoven, 205 USPQ 1069. Further, Paul et al. suggest the usefulness of ascorbic acid and arginine. Koff et al. further teaches that ascorbic acid is known for it's instability and unpleasant

taste and such problem may be overcome by coating ascorbic acid. See, the entire document, particularly, col. 1, lines 8-29. Therefore, use coated ascorbic acid in the composition would have been obvious at the time the claimed invention was made.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617